IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTY.'S DOCKET: IKEYA=1

In re Application of:	)	Confirmation No.: 3131
	)	
Hitoshii IKEYA et al	)	Group Art Unit: 1625
	)	
Appln. No. 10/591,653	)	Examiner: David E. Gallis
I.A. Appln. PCT/JP2005/003739	)	
	)	
§371 Date: 09/05/2006	)	Washington, D.C.
I.A. Filing Date: 03/04/2005	)	
	)	
For: HYALURONIC ACID-METHOTREXATE CONJUGATE	)	October 29, 2009

REPLY TO RESTRICTION REQUIREMENT

Customer Service Window, Mail Stop Amendment
Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Randolph Building, 401 Dulany Street
Alexandria, Virginia 22314

Sir:

Applicants are in receipt of the Office Action mailed October 2, 2009, mostly a restriction requirement based on U.S. practice. Applicants reply below.

Acknowledgment by the PTO of the receipt of Applicants' papers filed under §119 is noted.

Restriction has been required among what the PTO deems as being three patentably distinct inventions. As Applicants must make an election even though the requirement is traversed, Applicants hereby respectfully and provisionally elect Group I, presently claims 1-9 and 12-17, with traverse and without prejudice.

The present application is the U.S. National Phase of a Patent Cooperation Treaty (PCT) application, whereby normal U.S. restriction practice does not apply. Under these circumstances, unity of invention practice would apply under appropriate conditions where there were no unity of invention, noting MPEP 823 and 1896; also please see 37 CFR §§1.475 and 1.499. The PCT prohibits the present restriction requirement. In the present case, the applicable criteria which would apply if there were no unity of invention are set by PCT Rules 13.1 and 13.2.

Under the PCT unity of invention Rules 13.1 and 13.2, the criterion is "the same or corresponding special technical feature" or features. The present application meets this criterion in that the same or corresponding special technical feature which exists throughout all the claims is recited for example in claim 1.

The invention of Group I relates to a compound wherein methotrexate is conjugated with hyaluronic acid, a derivative or a salt thereof through a linker containing a peptide consisting of 1 to 8 amino acids. The invention of Group II relates to an intermediate to produce the compound of Group I, wherein methotrexate is linked with a linker containing a peptide chain of 1 to 8 amino acids. The invention of Group III is a process for producing the compound of Group I, by using the intermediate of Group II. Therefore, it is clear that these three groups have the same or corresponding special technical feature(s), and thus they fulfill the unity of invention requirement.

As unity of invention exists and as the restriction requirement is improper both in fact and under the law, Applicants respectfully request that it be withdrawn, and that all the claims be examined on the merits.

In paragraph 5 at the bottom of page 3 of the Office Action, the Examiner states that the claims in their present form are susceptible to a rejection under the second paragraph of §112, "…as claim 1 does not stipulate a starting material or a process of generating the hydrogen sulfate salt." Applicants do not understand the Examiner's commentary. The Group I claims, including claim 1, are drawn to a product, not a method. Applicants believe that stipulating a starting material or a process of generating any hydrogen sulfate salt would be inappropriate, and indeed improper.

Presently non-elected claim 11 does relate to a process, but the commentary of paragraph 5 still does not make any sense with respect to even claim 11.

Applicants respectfully request that the commentary of paragraph 5 at the bottom of page 3 of the Office Action be withdrawn.

Applicants respectfully await the results of an examination on the merits.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By 
Sheridan Neimark
Registration No. 20,520

SN:ltm
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\Y\YUAS\Ikeya1\Pto\2009-10-27 Draft Proposal.doc